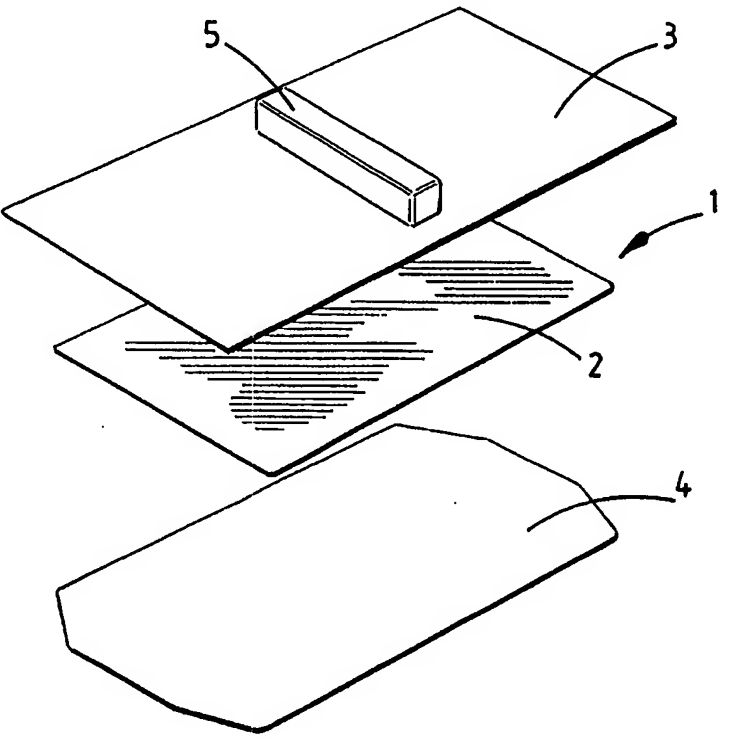




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(21) International Application Number: PCT/GB97/02896 (22) International Filing Date: 20 October 1997 (20.10.97) (30) Priority Data: 9621921.7 22 October 1996 (22.10.96) GB (71) Applicant (for all designated States except US): INNOVATIVE TECHNOLOGIES LIMITED [GB/GB]; Road Three, Winsford Industrial Estate, Winsford, Cheshire CW7 3PD (GB). (72) Inventors; and (75) Inventors/Applicants (for US only): LEAT, Martyn, Edward [GB/GB]; 5 Valley Gardens, Chapel Allerton, Leeds LS7 4QE (GB). RAFFERTY, Thomas, Brian [GB/GB]; 87 Kingsway, Widnes, Cheshire WA8 7QP (GB). O'BRIEN, Mark, Thomas [GB/GB]; 59 Walton Road, Sale M33 4AT (GB). HARDY, Craig, Julian [GB/GB]; 7 Bridgemere Court, Bridgemere, Nantwich, Cheshire CW5 7BX (GB). DIXON, Simon, Ashley [GB/GB]; "Highfield", Woolton Park, Woolton, Liverpool L25 6DR (GB). (74) Agent: ATKINSON, Peter, Birch; Marks & Clerk, Sussex House, 83-85 Mosley Street, Manchester M2 3LG (GB).		(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, HU, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG). Published <i>With international search report.</i>
(54) Title: FILM DELIVERY ASSEMBLY		
(57) Abstract <p>A film delivery assembly comprises a thin conformable film (2) having a first releasable carrier (3) attached to one of its surfaces and a biocompatible adhesive on the other. A second carrier (4) is attached to the adhesive coated surface less tenaciously than the first carrier is attached to the film. The first carrier has a handle portion (5) projecting, or movable to a position at which it projects, from the plane of the first carrier whereby the first carrier may be held by the handle portion with the film in a wrinkle-free condition to permit single handed positioning of the latter at the desired location.</p> 		

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FILM DELIVERY ASSEMBLY

The present invention relates to a film delivery assembly for use in medical applications. The invention relates more particularly to such an assembly incorporating a thin conformable film which is provided on one surface with an adhesive and which is to be applied to the body of a patient and adhered in position by the adhesive.

Thin conformable films are used for a number of medical applications, e.g. as a wound dressing or for locating a medical device in position on the body of a patient. Examples of such films are the moisture transmissive films available from Innovative Technologies Limited under the designations B53-2, C54-2 and D56-2. Films are also available from other manufacturers.

In view of their thin conformable nature, it is very difficult (if not impossible) satisfactorily to apply such films in an unsupported condition to the body of the patient. This is because the film may tend to wrinkle and adhere to itself by virtue of the adhesive on the film. Consequently the film is normally provided in a film delivery assembly, in which the film is sandwiched between two supporting layers, namely a first releasable carrier attached to the non-adhesive side (the "first surface") of the film and a second releasable carrier attached to the adhesive side (the "second surface") of the film. The first carrier (whilst still being releasable from the film) is attached more tenaciously to the film than is the second carrier.

To apply the film to the body of a patient, the second carrier is initially removed so as to leave the film supported in a wrinkle free condition by the first carrier. The adhesive side of the film may then be located in the position of the body of the patient and the first carrier subsequently removed. Thus the film is supported throughout the application.

We do however consider there to be a disadvantage with regard to the prior art delivery systems in that the first carrier is generally flat and, as such, it is necessary to use two hands to locate the combination of the film and first carrier in position before the latter is removed. This is particularly inconvenient since the person applying the dressing may also need to hold other items.

It is therefore an object of the present invention to obviate or mitigate the abovementioned disadvantages.

According to the present invention there is provided a film delivery assembly comprising

- (a) a thin conformable film having first and second surfaces
- (b) a first releasable carrier attached to the first surface of the film
- (c) a biocompatible adhesive on the second surface of the film, and
- (d) a second carrier attached to the adhesive coated second surface less tenaciously than said first carrier is attached to the first surface

wherein said first carrier has a handle portion projecting, or movable to a position at which it projects, from the plane of the first carrier whereby the first carrier may be held by the handle portion with the film in a wrinkle-free condition to permit single handed positioning of the latter at the desired location.

Therefore, in the film delivery assembly of the invention, the handle portion permits the first carrier to be held in the fingers of one hand so that (after removal of the second carrier) the first carrier may be positioned using the fingers of only one hand to apply the film at the desired location.

The handle portion may be provided in a number of ways. Thus, for example, the first carrier may be a flat sheet of material on which is mounted a handle on the side of the sheet opposite the film. Alternatively, the first carrier may be provided as two sheets which together entirely cover the first surface of the film and which at their juxtaposed edges have marginal flaps which are in face-to-face relationship to provide said handle. If the sheets are of a flexible material then the flaps may be folded about the juxtaposed edges of the sheets so as to lie flat against the first carrier and only be raised when required. This is particularly convenient for the purposes of providing a flat, packaged dressing.

In a further preferred embodiment, the first carrier may have at least one flap cut in the material of the carrier and foldable upwardly there from to form the handle or a part thereof. For preference the carrier comprises two such flaps which are foldably upwardly out of the plane of the carrier towards each other so as to be co-operable to form the handle. Conveniently the first carrier is provided in two separate sections with one flap being provided in each such section so that the sections may be removed from the film by pulling on their respective flaps.

In an alternative construction, the first carrier may be cut in a spiral formation attached to a central "eye" having opposed edges may be folded upwardly (out of the plane of the carrier) towards each other to form a handle. The first carrier may be removed from the film by pulling the handle away from the film whereby the turns of the spiral become progressively detached from the film.

The first carrier may for example be of paper or plastics material. In either case, the carrier may (but not necessarily) have a surface treatment to provide release properties. Thus for example the first carrier may be of siliconised polyester.

The film may be positioned on the first carrier by casting the film onto the material of the first carrier. Any cuts required in the first carrier may then be produced by "kiss-cutting" the carrier so that the cut does not penetrate into the film.

The second carrier may comprise two sheets which together entirely cover the second surface of the film and which at their juxtaposed edges have marginal flaps which are in face-to-face relationship so that these flaps may be gripped to remove the second carrier from the film.

The film is preferably a breathable film which is of increased MVTR capability in contact with liquid water as compared to moisture vapour only. MVTR in contact with liquid water may be measured by ASTM E96BW whereas MVTR in contact with moisture vapour alone may be measured by ASTM E96B (vapour contact method). Preferably the value of the breathability in contact with liquid water is at least twice and preferably at least three times that in contact with moisture vapour alone. The values may be up to 10 to 20 times that for moisture vapour alone. Typically the film will be of a material which has an MVTR in the presence of moisture vapour alone (ASTM E96B) of 1.000 to 5,000 $\text{g m}^{-2} \text{24hr}^{-1}$ and an MVTR in contact with liquid water (ASTM E96BW) in the range of 3.000 to 30.000 $\text{g m}^{-2} \text{24hr}^{-1}$ (e.g. 6,000 to 10,000 $\text{g m}^{-2} \text{24hr}^{-1}$). Typically the film will have a thickness of 20-70 microns more preferably 30-50 microns. e.g. about 40 microns.

The film may for example be of polyurethane. Suitable films are available from Innovative Technologies Limited under the designations B53-2, C54-2 and D56-2.

The adhesive on the second surface of the film may be provided as a continuous or discontinuous pattern to give any desired coverage up to 100%. The adhesive is preferably a hydroactive adhesive most preferably one which, as a continuous layer having a thickness of 20 microns, has an MVTR of 15.000 g m^{-2}

24hr⁻¹. Preferably the combination of the adhesive and film is such as to provide an MVTR of 6,000 to 10,000 g m⁻² 24 hr⁻¹.

The hydroactive adhesive may be provided as a continuous layer on the film. The adhesive is preferably applied in an amount of 2 to 40 g m⁻² 24 hr⁻¹.

Alternatively the adhesive may be a pressure sensitive adhesive, e.g. provided as a cross-hatched pattern to achieve 20-50% area coverage and to achieve similar MVTRs for the combination of adhesive and film of 6,000 to 10,000 g m⁻² 24 hr⁻¹.

Examples of suitable adhesives are those available from Innovative Technologies under the designations IT PSA HT or PSA LT.

The invention will be further described by way of example and with reference to the accompanying drawings, in which

Fig. 1 is an exploded perspective view of a first embodiment of film delivery assembly in accordance with the invention;

Fig. 2 is a perspective view of a second embodiment of film delivery assembly;

Fig. 3 is an exploded perspective view of a third embodiment of film delivery assembly;

Fig. 4 diagrammatically illustrates use of the assembly of Fig. 3;

Fig 5 is an exploded perspective view of a fourth embodiment of film delivery assembly;

Fig. 6 is a plan view (to a reduced scale) of the assembly shown in Fig. 5; and

Fig. 7 diagrammatically illustrates use of the assembly of Fig. 5.

Referring firstly to Fig. 1, the film delivery assembly 1 illustrated therein comprises a thin conformable film 2 provided on its lower (as viewed in Fig. 1) surface with a continuous or discontinuous adhesive layer. At its upper surface, the film 2 is attached to a first releasable carrier 3 whereas the adhesive coated surface of film 2 is attached to a second carrier 4. The carrier 3 is provided with a handle formation 5 and is bonded more tenaciously to the film 2 than is the carrier 4.

To apply the film 2 to a wound, the carrier 4 is firstly removed. The handle 5 may then be held in the figures of one hand so as to allow the combination of carrier 3 and film 2 to be located at a position at which film 2 may be applied to a wound. Once the film has been so applied, the carrier 3 may be removed.

It will therefore be appreciated that positioning and application of the film is substantially a one-handed operation so that one hand of the person applying the film remains free for other tasks.

Fig. 2 illustrates a further embodiment of the invention which incorporates a film 2 and carrier layer 4 as described for Fig. 1. The construction of Fig. 2 does however differ from that of Fig. 1 with regard to the first carrier. In the arrangement of Figure 2, the first carrier is provided as two sheets 6 and 7 which together entirely cover the upper surface of the film and which at their juxtaposed edges have respective marginal flaps 8 and 9 which are in face-to-face relationship to provide a handle formation. Sheet 6 and 7 may be of a flexible material so that the flaps 8 and 9 may be folded downwardly for the purposes of providing a flat, packaged dressing.

The arrangement of Figure 2 is used in exactly the same way as that of Figure 1 save that, once the film 2 has been applied to a wound, both sheets 6 and 7 need to be removed.

Reference is now made to Figs. 3 and 4 in which the illustrated film delivery assembly comprises a thin conformable film 20 which is sandwiched between first and second carrier assemblies 21 and 22 respectively. As with the constructions illustrated in Figs. 1 and 2, the film 20 has a continuous or discontinuous adhesive coating which is in contact with the second carrier 22.

The first carrier 21 is divided (by a cut 21a along the centre line of the carrier 21 into) two halves 23 each of which is formed with a generally semi-circular cut (extending through the thickness of carrier assembly 21 but not on to film 20) such that semi-circular flaps 24 are formed. These flaps 24 may be folded upwards out of the plane of carrier 21 about embossed lines 25.

The second carrier 22 is formed as two separate sheets 26 which together cover the film 20 and which at their juxtaposed edges have marginal flaps 27 in face-to-face relationship.

The use of the film delivery assembly of Fig. 3 is illustrated in Fig. 4. As shown in this latter figure, the semi-circular flaps 24 are raised (by folding about lines 25) from the plane of carrier 21 so that the two flaps 24 come into facing relationship thereby forming a handle 28 which enables the assembly to be held by the fingers of one hand. In the next step, the flaps 27 are gripped and peeled away from the film 20 (as illustrated in Fig. 4 (b)). It will be appreciated that the sheets 26 may be entirely removed from the delivery assembly at this stage.

With the remaining parts of the assembly still gripped (by handle 28) in the fingers of one hand, the film 20 may be located in position on a wound. Once the film

has been located, the flaps 24 are each pulled away from the centre line of the carrier assembly 21 whereby each portion 23 is removed from the film and may then be discarded.

To manufacture the assembly of Fig. 3, the flaps 24 may be formed after application of the material forming the first carrier sheet 21 to the film 20 by "kiss-cutting" the flaps 24 in the first carrier.

Reference is now made to the delivery assembly of Fig. 5 which differs from that of Fig. 3 with regard to the structure of its first carrier 30 which is described more fully below. However, in view of the other similarities between the constructions of Figs. 3 and 5, like parts in the two construction are represented by identical reference numerals.

The carrier 30 covers the non-adhesive side of film 20 and is "kiss-cut" in to the form of a "rectangular" spiral. More particularly, the spiral "begins" at one outer corner of carrier 30 and its arms extend generally parallel to the outer edges of the carrier whereby the spiral is of generally "rectangular" configuration. At its inner end, the arm of the spiral is attached to a generally rectangular "eye" which is sub-divided into two flap portions 31 by an embossed line 32 (see Fig. 6).

The use of the dressing is illustrated in Fig. 7.

Initially, the flaps 31 are raised (about fold line 32) so as to form a handle formation 33 (see Fig. 7(b)). This handle 33 may be gripped in the fingers of one hand.

Subsequently, the carrier 22 is removed in the manner described previously such that the film 20 may be applied to the wound.

Finally, handle 33 is pulled upwardly (see Fig. 7 (c)) so that the turns of the spiral are progressively pulled away from the film 20 whereby carrier 30 is removed therefrom.

For all illustrated embodiments, the film and adhesive may be of materials as described more fully above. Various carrier sheets may be of paper, card or plastics.

CLAIMS

1. A film delivery assembly comprising
 - (a) a thin conformable film having first and second surfaces
 - (b) a first releasable carrier attached to the first surface of the film
 - (c) a biocompatible adhesive on the second surface of the film, and
 - (d) a second carrier attached to the adhesive coated second surface less tenaciously than said first carrier is attached to the first surface

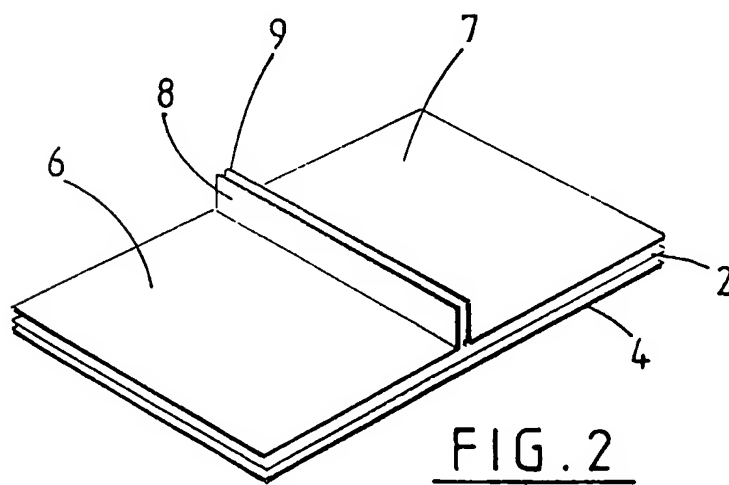
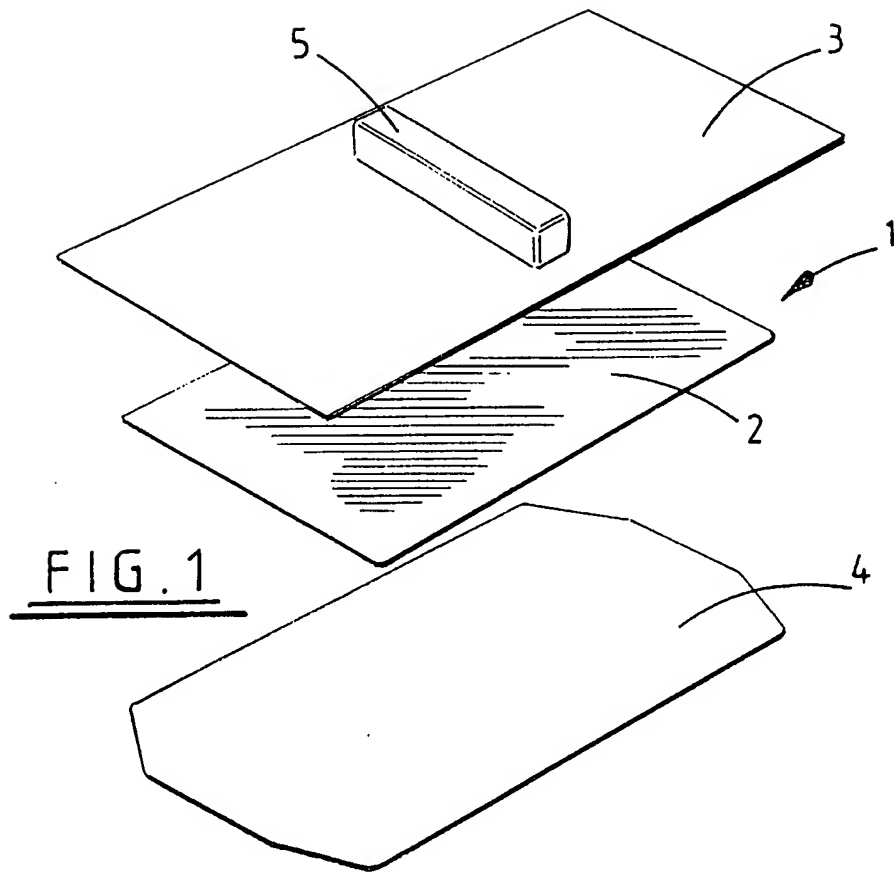
wherein said first carrier has a handle portion projecting, or movable to a position at which it projects, from the plane of the first carrier whereby the first carrier may be held by the handle portion with the film in a wrinkle-free condition to permit single handed positioning of the latter at the desired location.

2. An assembly as claimed in claim 1 wherein the first carrier is of a flat sheet of material on which is mounted a handle on the side of the sheet opposite the film.
3. An assembly as claimed in claim 1 wherein the first carrier is provided as two sheets which together entirely cover the first surface of the film and which at their juxtaposed edges have marginal flaps which are in face-to-face relationship to provide said handle.
4. An assembly as claimed in claim 3 wherein the sheets forming the first carrier are of a flexible material so that the flaps may be folded about the juxtaposed edges of the sheet so as to lie flat against the first carrier and only be raised when required.

5. An assembly as claimed in claim 1 wherein the first carrier has at least one flap cut in the material of the carrier and foldable upwardly therefrom to form the handle or part thereof.
6. An assembly as claimed in claim 5 wherein the carrier comprises two said flaps which are foldable upwardly out of the plane of the carrier towards each other so as to be cooperable to form the handle.
7. An assembly as claimed in claim 6 wherein the first carrier is provided in two separate sections with one flap being provided in each such section so that the sections may be removed from the film by pulling on their respective flaps.
8. An assembly as claimed in claim 1 wherein the first carrier is cut in a spiral formation which is attached at its inner end to a central "eye" having opposed edges which may be folded upwardly out of the plane of the carrier towards each other to form a handle.
9. An assembly as claimed in claim 8 wherein the film is generally rectangular and the arms of the spiral extend generally parallel to the sides of the film.
10. An assembly as claimed in any one of claims 1 to 9 wherein the first carrier is of paper or plastics material.
11. An assembly as claimed in any one of claims 1 to 10 wherein the second carrier comprises two sheets which together entirely cover the second surface of the film and which at their juxtaposed edges have marginal flaps which are in face-to-face relationship so that these flaps may be gripped to remove the second carrier from the film.

12. An assembly as claimed in any one of claims 1 to 11 wherein the film is a breathable film which is of increased MVTR capability in contact with liquid water as compared to moisture vapour only.
13. An assembly as claimed in claim 12 wherein the value of the breathability in contact with liquid water is at least twice and preferably at least three times that in contact with moisture vapour alone.
14. An assembly as claimed in any one of claim 13 wherein the film is of a material which has an MVTR in the presence of moisture vapour alone of 1,000 to 5,000 $\text{g m}^{-2} \text{24hr}^{-1}$ and an MVTR in the presence of liquid water in the range of 3,000 to 30,000 $\text{g m}^{-2} \text{24hr}^{-1}$.
15. An assembly as claimed in claim 14 wherein the film is of a polyurethane.
16. An assembly as claimed in any one of claims 1 to 15 wherein the film has a thickness of 20 to 70 microns.
17. An assembly as claimed in any one of claims 1 to 16 wherein the adhesive is a pressure sensitive adhesive.
18. An assembly as claimed in any one of claims 1 to 16 wherein the adhesive is a hydroactive adhesive.

1-5



2—5

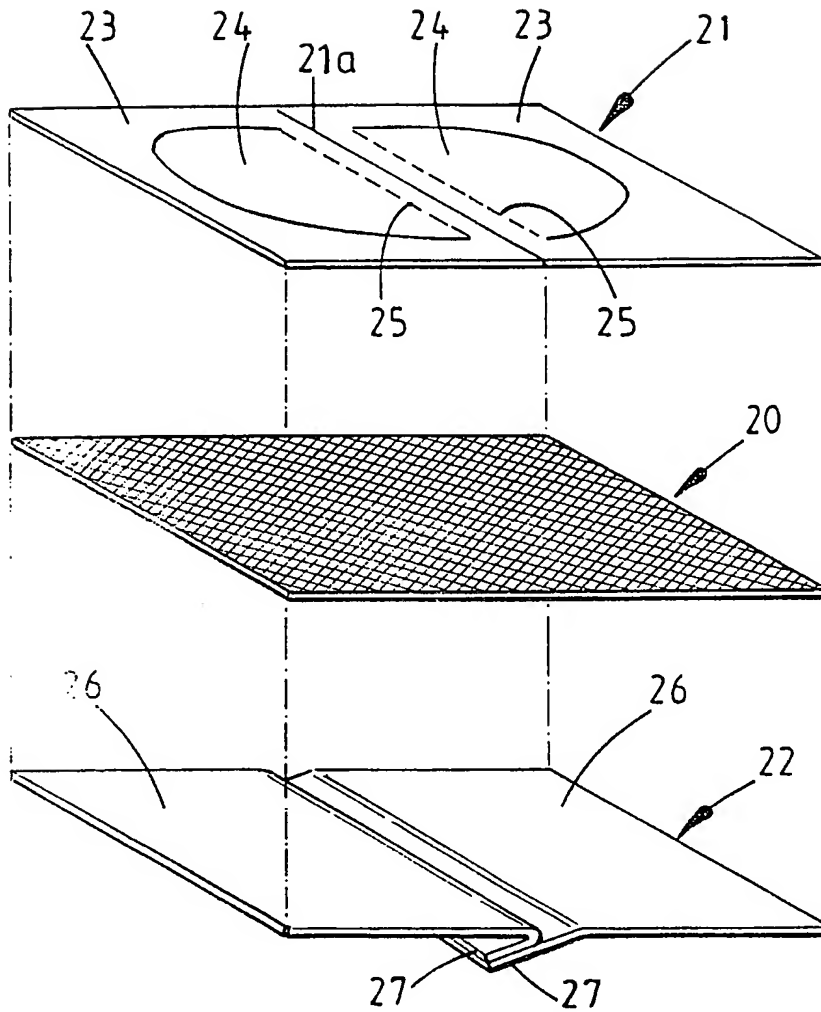


FIG. 3

3-5

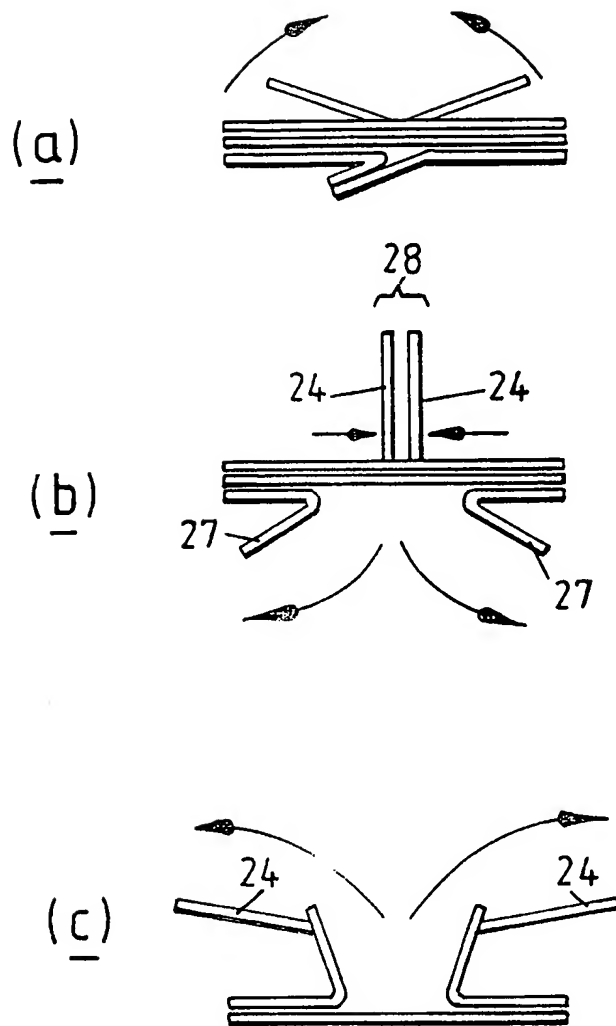


FIG. 4

4-5

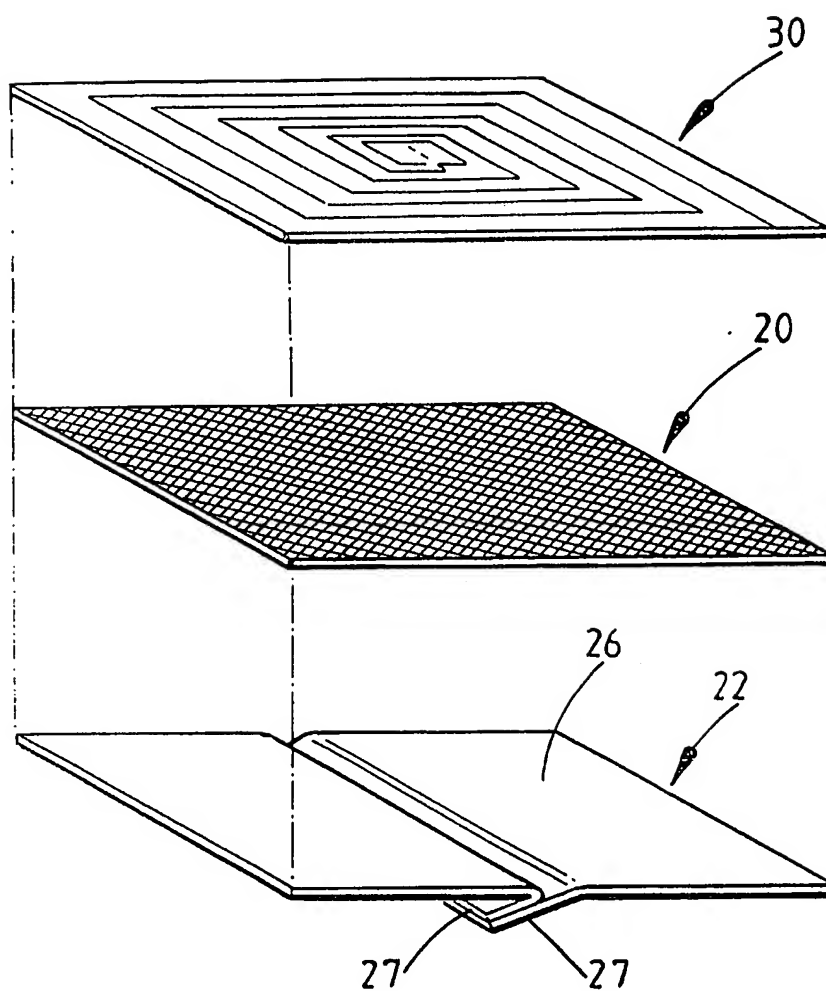


FIG. 5

5-5

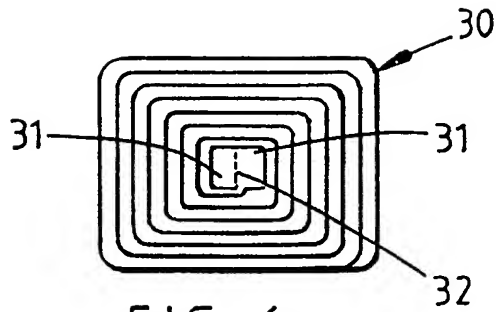
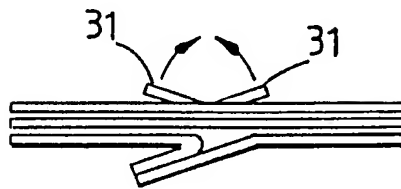
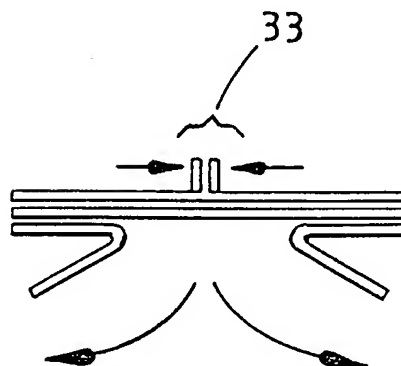


FIG. 6

(a)



(b)



(c)

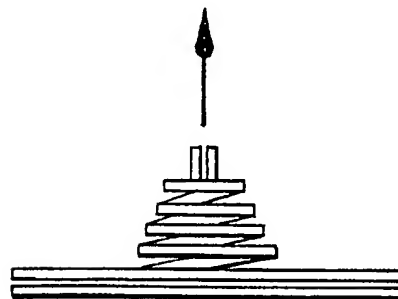


FIG. 7

INTERNATIONAL SEARCH REPORT

International Application No

PCT/GB 97/02896

A. CLASSIFICATION OF SUBJECT MATTER

IPC 6 A61F13/02

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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Y, P	WO 97 07760 A (INNOVATIVE TECH LTD ; GILDING KEITH DENIS (GB); BRENNALL RONALD EUG) 6 March 1997 see the whole document	11-18
A	---	1
A	WO 96 22753 A (INNOVATIVE TECH LTD ; GILDING DENIS KEITH (GB)) 1 August 1996 see claims	11-18

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Date of the actual completion of the international search

30 January 1998

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INTERNATIONAL SEARCH REPORT

International Application No

PCT/GB 97/02896

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages.	Relevant to claim No.
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International Application No

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